2017 CANADIAN PRESCRIBER SURVEY

Since its establishment in 2010, ASBM has used physician surveys to gather the perspectives of biologic prescribers in twelve countries, to help guide regulators and policymakers as they draft policies regarding biosimilars. These findings have been shared with national and international regulators worldwide. The full results of this survey and ASBM's other surveys may be viewed at www.SafeBiologics.org/surveys.

SURVEY OBJECTIVES

- Provide empirical data to Health Canada, provincial policymakers, and other regulatory agencies on the perspectives of Canadian prescribers of biologic medicines
- Measure physician familiarity and understanding of biosimilars, including their approval process
- Assess the implications of a biosimilar sharing a nonproprietary name with its reference innovator product
- Determine how physicians identify biologics in patient records and when reporting adverse events
- Gather physician perspectives on the importance of distinguishable naming
- Gauge physician attitudes on automatic substitution and non-medical switching

METHODOLOGY

ASBM surveyed 403 Canadian prescribers of biologics with a 15-minute web survey. Respondents were selected from 13 therapeutic specialties, including: Allergy/Immunology (3%), Dermatology (21%), Endocrinology (9%), Gastroenterology (9%) Hematology/Oncology (5%), Infectious Diseases (1%), Internal Medicine (19%), Nephrology (3%), Neurology (5%), Oncology (9%), Respiratory/Pulmonology (6%), Rheumatology (10%), and Urology (2%). All prescribe biologic medicines in their practice.

FAMILIARITY WITH BIOSIMILARS

Physician understanding and knowledge of biosimilars has improved significantly since ASBM conducted its first Canadian Prescriber Survey in 2014. For example:

- In 2014, 10% of respondents were very familiar with biosimilars, 48% familiar, 31% had heard of them but could not define them, and 10% had not heard of them.
- in 2017, 28% of respondents were very familiar with biosimilars, 55% familiar, 14% had heard of them but could not define them, and 3% had not heard of them.

DISTINCT NAMING

The results showed a strong physician preference for distinct naming of biologics and biosimilars, but no consensus on the best approach:

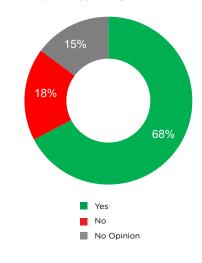
- 68% supported Health Canada issuing a distinct nonproprietary name for every biologic, including biosimilars.
- 50% considered a completely different nonproprietary name the best method of differentiating a biosimilar from its reference product, with 31% preferred a differentiating prefix, 11% a differentiating suffix, and 7% a shared INN with a manufacturer code.

IMPLICATIONS OF SHARED NONPROPRIETARY NAMES

 54% believe biosimilar which shares an INN with its reference product implies the two are structurally identical, which is not the case.

63% believe a biosimilar which shares an INN with its reference product implied the two were approved for the same indications. This may or may not be the case.

"In your opinion, should Health Canada insist on a **DISTINCT NON-PROPRIETARY / GENERIC NAME** for every biologic or biosimilar product approved by them?"



ADVERSE EVENT REPORTING

- When reporting adverse events, 26% of physicians referred to the product only by its INN, which could result in misattribution to the incorrect product.
- Only 23% consistently recorded the batch number when reporting adverse events, and 36% rarely or never recorded it.

NON-MEDICAL SWITCHING

- 64% were not comfortable with a third party switching a patient's medicine for non-medical reasons. 28% are somewhat comfortable, and only 6% were completely comfortable.
- 33% are not comfortable if a patient is switched for non-medical reasons, even if they themselves conduct the switch, 51% are somewhat comfortable, and only 12% were completely comfortable.

PHARMACY SUBSTITITION

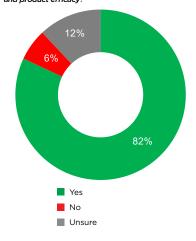
Maintaining prescribing autonomy was found to be extremely important to Canadian physicians:

- 83% considered it "very important" or "critical" that the prescribing physician decide the most suitable biologic for their patients.
- 78% considered it "very important" or "critical" to be notified in the event a biosimilar is substituted at the pharmacy.
- 79% considered it "very important" or "critical" to have the authority to designate on a prescription for a biologic medicine "Dispense as Written" or "Do Not Substitute".
- 82% of prescribers believe switching studies should be conducted which measure the effects of switching on patient safety and product efficacy, prior to deciding whether automatic substitution should be allowed by a pharmacist or payer.

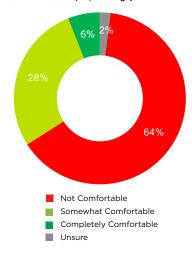
CONCLUSIONS

- Physician knowledge and understanding of biosimilars has improved significantly over the past three years.
- Misconceptions about biosimilars, along with physician prescribing and recording practices, highlight the need for distinct naming of all biologics, including biosimilars.
- Physicians overwhelmingly (68%) support Health Canada implementing distinguishable names, however there is no consensus as to best approach.
- Physicians are generally open to substituting biosimilars for non-medical reasons, but generally uncomfortable with this being done by a third party. DAW authority and notification in the event of a substitution remain of high importance.
- Physicians overwhelmingly (82%) support switching studies The Alliance for Safe Biologic Medicines is a diverse group of stakeholders including physicians, pharmacists, patients, researchers, and manufacturers of both biologics and biosimilars. ASBM is an organization focused on promoting the use of biologic medicines, while ensuring their safety and efficacy. Learn more at www.safebiologics.org.

"Prior to deciding whether automatic substitution should be allowed by a pharmacist or payer, do you believe STUDIES SHOULD BE CONDUCTED that measure the effects of switching on patient safety and product efficacy?"



"How comfortable are you with a THIRD-PARTY SWITCHING your patient to a biosimilar for NON-MEDICAL REASONS (i.e., coverage)?"



"In a situation where substitution by a pharmacist was an option in your province, how important would it be to you to have the authority to designate a biologic medicine as 'DISPENSE AS WRITTEN' or 'DO NOT SUBSTITUTE'?"

